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10/802,166	03/17/2004	James Robert Schwartz	9184M	4150
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
	10/802,166	SCHWARTZ ET AL.	
Office Action Summary	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	
The MAILING DATE of this communication ap	ppears on the cover sheet with the	correspondence address	
Period for Reply	VIO OET TO EVEIDE AMONTH	(O) OD TUBETY (OO) DAYO	
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING ID.  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO .136(a). In no event, however, may a reply be tid d will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE	N. mely filed n the mailing date of this communication. ED (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed on 30 I      This action is <b>FINAL</b> . 2b) ☑ This      Since this application is in condition for allowed closed in accordance with the practice under	is action is non-final. ance except for formal matters, pr		
Disposition of Claims			
4) Claim(s) 1,3,7-13 and 15-27 is/are pending in 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed.  6) Claim(s) 1, 3, 7-13 and 15-27 is/are rejected 7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/	awn from consideration.		
Application Papers			
9) The specification is objected to by the Examin 10) The drawing(s) filed on is/are: a) ac Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E	cepted or b) objected to by the edrawing(s) be held in abeyance. Section is required if the drawing(s) is ob	ee 37 CFR 1.85(a). pjected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreig  a) All b) Some * c) None of:  1. Certified copies of the priority documer  2. Certified copies of the priority documer  3. Copies of the certified copies of the priority application from the International Burea  * See the attached detailed Office action for a lis	nts have been received. nts have been received in Applicat ority documents have been receiv au (PCT Rule 17.2(a)).	tion No red in this National Stage	
Attachment(s)	_		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal I 6)  Other:	Date	

#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/09 has been entered.

Claims 2, 4-6 and 14 have been cancelled. Claims 1, 3, 7-13 and 15-27 are pending and under examination.

#### Terminal Disclaimer

The Examiner notes the filing of a terminal disclaimer over co-pending application 10/803126. However, the terminal disclaimer has not as yet been approved.

#### Withdrawn rejections:

Applicant's amendments and arguments filed 11/30/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 1, 3, 7-13, and 18-25 were rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151) as evidenced by the Wikipedia Zinc Oxide. Applicant has amended the claims to overcome this rejection. Accordingly, it is withdrawn.

Claims 1, 3, 7, 8-13, 20 and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Wiese (US 5,227,156) as evidenced by the Wikipedia Zinc Oxide. Applicant has amended the claims to overcome this rejection. Accordingly, it is withdrawn.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The claims recite: "...the use of the composition of Claim 1." A claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). As a result, the Applicants are respectfully required to redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 7-13 and 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 9, 26 and 27 recite: "greater than about". The term 'greater than' a value provides a static point while the term 'about' a value provides a dynamic point which can be a little more or less than the value. The value cannot be simultaneously static and dynamic and therefore the claims are indefinite. The claims will be examined as they read on

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"greater than". Claims 3, 7, 8, 10-13 and 15-25 are rejected as being indefinite because they are dependent on an indefinite base claim.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 7-13 and 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) and Bhat et al. (WO 96/25913).

Applicant claims:

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(currently amended) A composition comprising:

- a) from about 0.001% to about 5 % of a zinc-containing layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydroxide, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof:
- b) from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group;
  - c) from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione;

wherein the zine-containing layered material has a relative zine lability of greater than about 15% and further wherein the ratio of surfactant to zine-containing layered material is greater than or equal to 2 to 1.

## Determination of the scope and content of the prior art

## (MPEP 2141.01)

Gavin et al. teach a topical anti-dandruff composition for treating microbes comprising:

- From 0.001% to 10% zinc pyrithione or polyvalent metal salts of pyrithione;
- from 0.001 to about 10% of a metal ion source such as zinc salt or copper salt or mixtures thereof; and
- o an anionic detersive surfactant (about 5 to about 50% by weight) for a topical carrier (Page 8, lines 10-15 and Claim 1).

Less than 50% of the polyvalent metal salt dissociates into free pyrithione in the composition (claim 2). The ratio of surfactant to zinc containing layered material can be greater

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than or equal to 2 to 1 by simple manipulation of the amounts taught above. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The addition of cationic deposition polymers (instant claim 18) is taught (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is taught (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence reading on the method of instant claims 23-25 (Claim 9).

Bhat et al. teach personal care product compositions comprising a surfactant and the zinc salt monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2). The structure of the zinc compound is Zn<sub>5</sub>(OH)<sub>6</sub>(CO<sub>3</sub>)<sub>2</sub> X H<sub>2</sub>O where X varies between 0 and 4 (Page 6, lines 23-27). When X=0 then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Indeed, Bhat et al. teach release of zinc ions from zinc hydroxycarbonate (page 7, lines 31-35). Bhat et al. teach synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos (page 8, lines 1-4). Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

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Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Gavin et al. do not expressly teach a composition comprising as the zinc containing layered material basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof that has a zinc lability of greater than 15%, 20% or 25%. This deficiency in Gavin et al. is cured by the teachings of Bhat et al.

### Finding of prima facie obviousness

## **Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Gavin et al. comprising as the zinc containing layered material basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof that has a zinc lability of greater than 15%, 20% or 25%, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition but not specifically basic zinc carbonate or zinc carbonate hydroxide, for example, and Bhat et al. cure this deficiency by teaching the *synergistic* 

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action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos.

One of ordinary skill in the art would desire the synergistic action of the zinc hydroxycarbonate with the anti-dandruff active zinc pyrithione in the composition to produce the best results. The 'zinc lability' is an intrinsic property of the zinc salts since they are the same as instantly claimed. With regards to the other zinc and copper salts, it is merely judicious selection of zinc and copper salts by one of ordinary skill in the art in the absence of evidence to the contrary. One of ordinary skill in the art would have had a reasonable expectation of success because it appears that any zinc or copper or mixed zinc-copper salt will work in this invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

# Response to arguments:

Applicant asserts that Bhat teaches that "zinc hydroxycarbonate shows synergistic antimicrobial activity with detergents such as sodium lauryl sulphate." This is correct. However, Bhat also teach synergistic action with zinc pyrithione (see above). The motivation to combine

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Bhat with Gavin is to obtain that synergistic activity in the composition of Gavin. Applicant's arguments are not persuasive.

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3, 4, 7-13, 15-17 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, 11, 12, 14-17, 21 and 23-25of copending Application No. 10/803126. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses methods of treating microbial infections, fungal infections and dandruff with a composition comprising from about 0.01% to about 5% of a polyvalent metal salt of pyrithione (zinc pyrithione) and from about 0.001% to about 10% of a zinc layered

material basic zinc carbonate. The copending application teaches personal care compositions such as shampoo and soaps.

The copending application does not expressly disclose adding from about 10 to 50% of the total composition of anionic surfactants to provide a ratio of surfactant to zinc layered material of greater than or equal to 2:1, pH greater than 6.5 or from about 6.8 to about 9.5 and relative zinc lability.

However, the open language of the copending application allows for the addition of anionic functional group surfactants to shampoo and soaps compositions and it is within the skill of one of ordinary skill in the art to optimize the amount of surfactant in the composition to produce the desired result and produce the instantly claimed ratio. Measurement of pH is routine in solution formulation and merely judicious selection of components to arrive at the instantly claimed pH. Relative zinc lability is intrinsic in the basic zinc carbonate.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## **Response to arguments:**

Applicant has filed a terminal disclaimer which has not as yet been approved. Until it is approved the Examiner must maintain the rejection.

2. Claims 1, 3, 7-13, 15-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-12, 16-32, and 34-39 of copending Application No. 11/602770. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions, shampoo and methods of treating dandruff with an effective amount of a particulate zinc material (such as basic zinc carbonate); 0.01-5% zinc pyrithione, 1-50% anionic surfactants. The copending application discloses cationic deposition polymers, conditioning agents, suspending agents, pH ranges, relative zinc labilities and various surfactants.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Response to arguments:**

Applicant requests that this rejection be held in abeyance until allowable subject matter is indicated. Until that time the rejection is maintained.

3. Claims 1, 3, 7-13, 15-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 13-130, 35 and 37-40 of copending Application No. 11/890684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter

embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff comprising a particulate zinc material (basic zinc carbonate as well as every other zinc layered material instantly claimed (see claims 25 and 26)); 0.01 to about 5% zinc pyrithione; 1% to about 50% anionic surfactant; pH; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Response to arguments:**

Applicant asserts that the instant invention is not drawn to a composition containing water soluble or dispersible, cationic, non-crosslinked conditioning homopolymer having a cationic charge density. However, the instant open language allows for additional ingredients. Furthermore, the copending application positively recites the same components as instantly claimed including anionic surfactants (claim 17). Applicant asserts that the copending application does not require a relative zinc lability of greater than about 15% or the zinc layered material selected from the instant elements. The Examiner directs applicant's attention to claims 25 and 26 of the copending application which teach the same zinc layered materials which

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intrinsically have the same zinc lability. Applicant's arguments concerning lyotropic liquid crystals is not persuasive as the instant claims do not exclude such forms. Applicant's arguments are not persuasive.

4. Claims 1, 3, 7-13, and 15-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff, fungal and microbial infections comprising a 0.001% to about 10% zinc containing material (basic zinc carbonate); 0.01 to about 5% zinc pyrithione; 5% to about 50% anionic surfactant; pH is greater than about 7; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Response to arguments:**

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Applicant asserts that the instant application is directed to zinc containing layered materials and not zinc materials with an aqueous solubility of less than about 25% by weight at 25 °C. However, the copending application recites basic zinc carbonate which intrinsically meets the instant limitations as well as all of the instantly claimed zinc layered species (see claims 11 and 12). Applicant's arguments are not persuasive and the rejection is maintained.

5. Claims 1, 3, 7-13, 15-22, 26 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, 10-14, 17-21 of U.S. Patent No. 7026308 in view of Bhat et al. (WO 96/25913). The reference of Bhat et al. is discussed in detail above and that discussion is hereby incorporated by reference. The '308 patent discloses a topical composition comprising zinc pyrithione, zinc salts, anionic surfactants and cationic deposition polymers.

The '308 patent does not expressly teach the zinc salt as basic zinc carbonate or zinc hydroxycarbonate with a relative zinc lability of greater than 15, 20 or 25%. However, Bhat et al. teach the synergistic action of adding basic zinc carbonate or zinc hydroxycarbonate to compositions with zinc pyrithione and the zinc lability would be intrinsic to the materials.

Therefore, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patent and had a reasonable expectation of success.

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## Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 6:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/ Primary Examiner, Art Unit 1616